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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
1641	5

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/823,183	Applicant(s) REARDON, PAUL C.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite with respect to the contacting steps. "Contacting" implies method steps, however, on closer inspection, they appear to be steps reciting the location of the various pieces of the device. Correction is required.

Claim 1 is further confusing with respect to the reagent in the control reaction site. Is this reagent non-diffusively or diffusively immobilized in this location?

Claim 2, "the presence of whole antibody" lacks antecedent support. It is also unclear how the whole antibody is related to the chromogenic mobile specific binding partner? Since these are method claims, the relationship between each of the reagent must be clearly recited.

Claim 3 is confusing because of the use of improper Markush language. Further, it is unclear exactly what "free kappa chains", etc., is being claimed. Are they free kappa chain of IgG, etc.?

Claims 6 and 7 are confusing because of the use of improper Markush language.

Claim 7 is further confusing with respect to the recitation of " for performing a competitive analysis" because it is unclear what the other reagents are that would allow for such an analysis.

Claims 8 and 9 are confusing with respect to the recitation of "specific binding reagent" because they read on both the reagent in the first reagent site and the control reaction site. Clarification is required.

Claim 9 is further confusing with respect to the recitation of "for the detection of immunochemicals", what immunochemicals? Are these chemicals different from the analytes?

Claim 10, "said second reaction site" lacks antecedent support. "The presence of whole antibody" also lacks antecedent support. It is also unclear how the whole antibody is related to the analytes. Since these are method claims, the relationship between each of the reagent must be clearly recited.

Claim 13 is confusing because it appears that all three reaction sites have the same immobilized specific binding reagent because they are recited as being able to bind the same chromogenic mobile specific binding partner, however, these binding reagents are designed as second and third, etc., implying that they are different binding reagents. Clarification is required.

Claim 15 is confusing because of the use of improper Markush language. Further, it is unclear exactly what "free kappa chains" etc., is being claimed. Are they free kappa chain of IgG, etc.?

Claim 20 is confusing because of the use of improper Markush language.

Claim 21 is confusing because it is unclear which immobilized specific binding reagent is being claimed. The one in the first reaction site?

Claim 23 is confusing because of the use of improper Markush language.

Claim 24 is confusing because the relationship between the analyte and the chromogenic specific binding partner and the specific binding partner in the first and second reaction sites have not been clearly defined. Claim 13 indicates that the specific binding partner in the first and second reaction sites binds to the chromogenic specific binding partner in relation to the presence of the analyte in the sample, this does not positively indicates that the specific binding

partner in the first and second reaction sites bind to a complex comprising the chromogenic specific binding partner and the analyte, thus, a detection of label at the first and second reaction sites does not indicate the presence of analyte as claimed in claim 24.

Claim 26 is confusing with respect to the specific binding reagent in the second reaction site. Is this agent immobilized in the second reagent site? Further, it appears that the binding agents in both the first and second reaction sites are the same. Clarification is required.

Claims 28 and 29 are confusing with respect to the use of improper Markush language.

Claim 29 is further confusing because it is unclear exactly what "free kappa chains", etc, is being claimed. Are they free kappa chain of IgG, etc.?

Claim 30 is confusing because it is unclear which specific binding agent is being claimed.

Claim 31 is confusing because it is unclear what exactly constitute "free light chains and classes thereof". Free light chains of what?

Claims 35 and 38, "said reaction" lacks antecedent support. It appears that the word --tube-- is missing from this phrase.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 4, 5, 11-19, 24-27, 31 and 32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by May et al (GB 2,204,398).

May teaches an assay device comprising a hollow casing constructed of moisture-impervious solid material. The device contains a dry porous carrier that communicates directly or indirectly with the exterior of the casing. Urine test sample may be applied to the porous carrier. The device containing a labeled specific binding reagent for an analyte that is freely mobile within the porous carrier when in the moist state, and unlabeled specific binding reagent for the same analyte that is permanently immobilized in a detection zone on the carrier material (page 3). May teaches an embodiment of the invention in which a dry porous nitrocellulose carrier communicates indirectly with the exterior of the casing via a bibulous urine receiving member that protrudes from the casing and can act as a reservoir from which urine is released into the porous carrier (page 7, lines 23-29, see also figure 9 and description on page 23). The device also contains a control zone loaded with an antibody that will bind to the labeled antibody from the first zone. The control zone may also contains an anhydrous reagent that when moistened, produces a color change or color formation. Or as an alternative, the control zone could contain immobilized analyte that will react with excess labeled reagents from the first zone (page 9). May teaches the use of direct labels such as minute colored particles, such as dye sols, metallic sols and colored latex particles (page 10). May teaches a plurality of detection zones arranged in series on the porous solid phase material through which the aqueous liquid sample can pass progressively, can also be used to provide a quantitative measurement of the analyte or can be loaded individually with different specific binding agents to provide a multi-analyte test (page 11). Quantitative measurement may be done visually by eye or by instrument (page 10, lines 10-13). May teaches backing the porous nitrocellulose sheet with plastic to increase handling strength (page 13). May also teaches an absorbant sink provided at the distal end of the carrier material to aid in the flow of sample and to ensure that excess labeled reagent

from the first zone which does not participate in any binding reaction in the second zone is flushed away from the detection zone (page 11, lines 1-17).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 3, 6, 7, 8, 10, 20, 21, 23, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over May in view of Massaro (US 5,141,877).

See the discussion of May above. May differs from the instant invention in failing to teach the detection of analytes such as free and bound kappa and lambda chains of immunoglobulins.

Massaro, however, teaches the detection of Bence Jones proteins (i.e. free light chains of immunoglobulins) in urine samples. Massaro teaches that the presence of said light chains in the urine is an indication of the existence of a pathological condition (column 1, lines 6-34).

Massaro teaches that two types of light chains, kappa and lambda, may be determined from urine (column 2, lines 28-31) using antigen-antibody turbidity reaction methods.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of May to include reagents for the detection of Bence Jones proteins such as taught by Massaro. May teaches that their device may be modified to detect a wide variety of analytes by choice of appropriate specific binding reagents (page 17, lines 4-6) and Massaro teaches that the detection of Bence Jones proteins in the urine is advantageous because it provides a diagnosis of the existence of a pathological condition. A skilled artisan would have had a reasonable expectation of success in using the modified device of May to detect Bence Jones proteins because May teaches that their device provides the advantage of a simple one step device that may be used by an unskilled person giving a result which is rapid and which requires the minimum degree of skilled and involvement from the user (page 1).

6. Claims 9, 22 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over May in view of Massaro as applied to claims 1-8, 10-21, 23-29, 31 and 32 above, and further in view of Brizgys et al (US 5,807,752).

See the discussion of May and Massaro above. These references differ from the instant invention in failing to teach the use of Protein A.

Brizgys, however, teaches a test system for determining one or more analytes, such as different antibodies isotypes, in a sample (column 3, lines 21-28 and 49-50). Brizgys teaches capture and labeled receptors for the antibodies such as antibodies, antigens and Protein A, etc. (column 4, lines 32-39).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Protein A taught by Brizgys in the modify device and method of May because Brizgys teaches the Protein A is well known in the art for binding to heavy and light chains of immunoglobulins. The use of protein A also provides the advantages of a universal specific binding reagent for the detection of different isotypes of antibodies.

7. Claims 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over May in view of Massaro as applied to claims 1-8, 10-21, 23-29 and 31-32 above, and further in view of Deutsch et al (US 4,094,647).

See the discussion of May and Massaro above. These references differ from the instant invention in failing to teach a kit comprising a reaction tube.

Deutsch, however, teaches a similar test device, and in addition, teaches a test tube for holding the test device while the assay progress. Deutsch teaches that the size f the test tube and the dimensions of the test strip may be selected so that the volume of fluid is precisely the amount that is taken up by the test strip. See column 5, lines 46-63.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to assemble the device of May as modified by Massaro, and the test tube of Deutsch into a kit as taught by May. The advantages of assembling various reagents into a kits are well known in the art as providing convenience and economy. Even though the test tube taught by Deutsch is for holding a developing liquid and not a urine sample, it is still deemed to render obvious the instant claims because the intended use of a device is not given patentable weight.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
March 25, 2002